Allergy Therapeutics PLC

# Delivering on our strategy

JP Morgan 2021

Manuel Llobet, Chief Executive Officer Nick Wykeman, Chief Financial Officer Alan Bullimore, Head of Business Innovation



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#### **Allergy Therapeutics**

Unique Selling Point - Ultrashort course treatment technology platforms

Potential to cure, not just treat symptoms

Only truly innovating business in broad allergy market of biotechnology

Large US market potential in peanut, allergic rhinitis and immunotherapy

Successful trading model - 9% annual revenue growth over the last 22 years

Leading aluminium-free subcutaneous allergy vaccines

Rich pipeline with both near market and early stage candidates

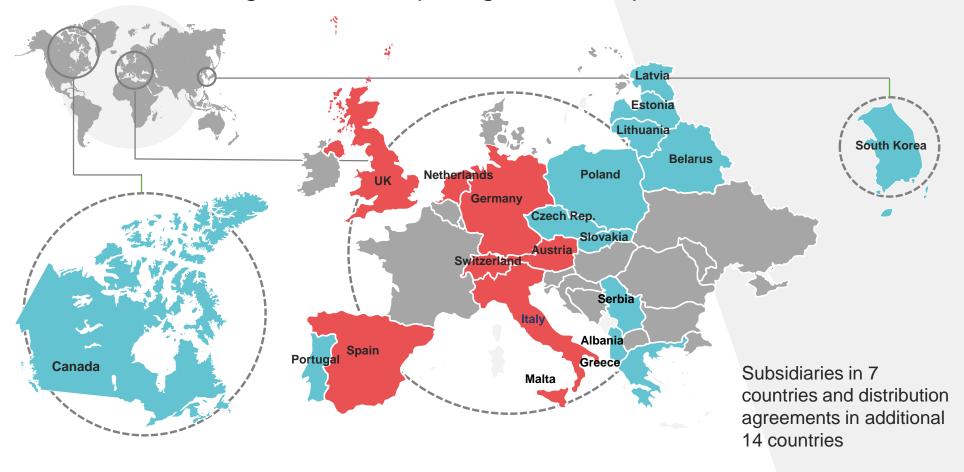
Listed on London Stock Exchange (AIM)



#### Allergy Therapeutics PLC

## Allergy Therapeutics: Company with Solid Sales and Global presence

Sales and marketing network comprising c.140 European sales force



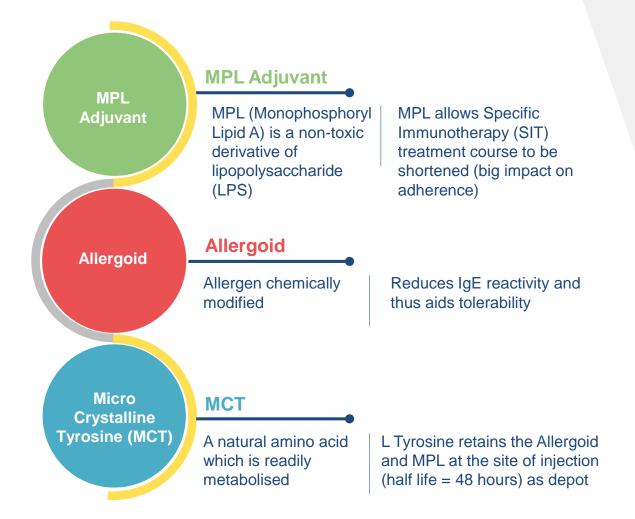


#### **Platforms**



# PQ: Differentiated platform approach enhances compliance, leads to higher efficacy and successful outcomes





- VLP platform has potential in many different allergy areas.
- Sophisticated technology with potential to treat severe and extreme allergies
  - Engineered with a T-cell epitope derived from the tetanus toxin
  - Leads to activation of memory cells
  - Increased antibody response
- When bound with an allergen, the immune system reacts to the virus not the allergen.
- Therefore protective immunity is induced, enabling shorter therapy duration with an enhanced tolerability profile.

Potential allergy areas include peanut, mixed nuts, cat, mould, mite and venoms

Initial peanut results show potential of technology

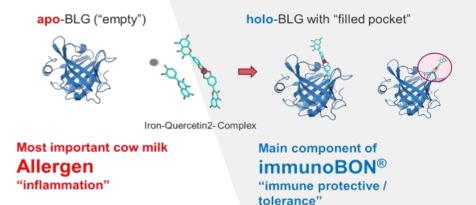
#### Science of immunoBON®

#### What we already know:

- "raw milk-effect": raw milk protects from allergies
- "farm-effect" based on "Hygiene hypothesis": living close to traditional cattle farms protects from allergies

#### What is new:

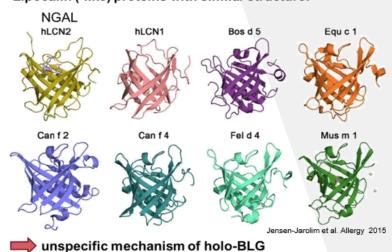
- Lipocalins, that are found in raw milk and farm dust, are proteins that can protect from allergy.
- > B-lactoglobulin (BLG) in its holo-form binds iron.
  - ➤ Holo-BLG:
  - immune response ↓
  - allergies ↓



Roth-Walter F., et al. Metallomics. 2017; 9(12):1676-1692

Roth-Walter et al. PLOS one, 2014

#### Lipocalin (-like) proteins with similar structure:



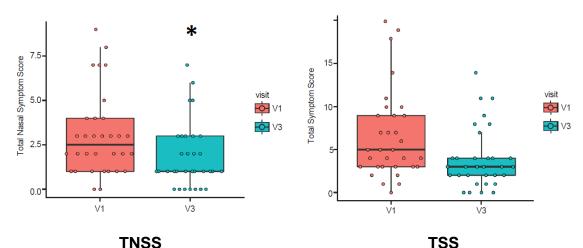
unspecific mechanism of holo-BLG broad application (different allergies)

#### immunoBON® clinical studies

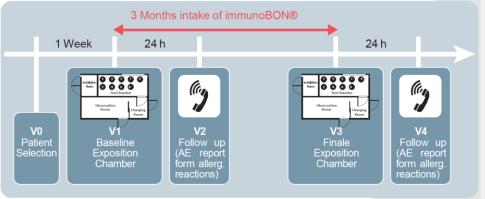
#### **Study overview:**

We assessed the effect of a new dietary supplement (immunoBON®) containing whey proteins such as BLG, iron, retinoic acid, zinc and polyphenols on participants suffering from house dust mite (HDM) induced allergic rhinoconjunctivitis.

#### **Results:**



#### Study Design:



The primary endpoint (total nasal symptom score "TNSS") revealed significant improvement after intake of immunoBON®.

The Median TNSS was decreased by 60% (p=0.0034) and the Median Total Symptom Score "TSS" by 40% (p=0.0026)

This is the first evaluation of a novel immune modulating dietary supplement (immunoBON®) in a highly standardized allergen exposure chamber (AEC) setting, demonstrating beneficial effects especially on nasal, ocular and bronchial symptoms in HDM allergic patients. After an intake period of only 3 months the primary endpoint defined as the change in Median Total Nasal Symptom Score (TNSS) after 120 minutes of HDM exposure in the AEC was significantly reduced by 60%.

#### Allergy Therapeutics PLC

# Three Pillars to Growth: Advancing a Leading Allergy Immunotherapy Company

<u>01</u>

#### Strong pipeline

New technologies underpin pipeline breadth and depth

Investment strategy supported by growing revenue stream



02

#### Expanding in Europe

Strongly performing profitable business

Growing market share and additional product registrations

Drive market position via world class supply chain and increased patient adherence



03

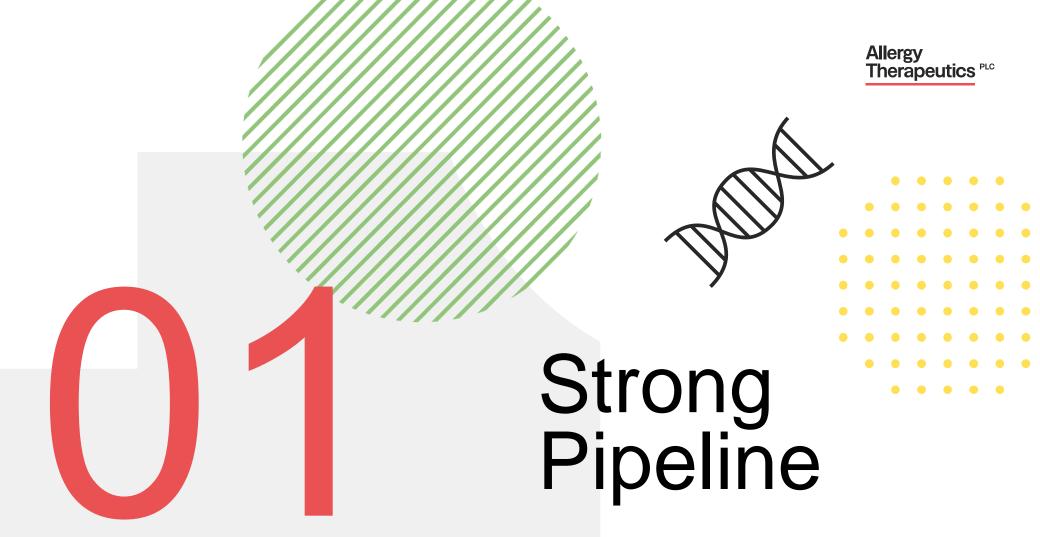
#### Preparing for US entry

Significant opportunity in largest allergy market

Develop market access approach and relationships

Changing regulatory and reimbursement environment to drive market share towards Allergy's products





#### **Innovative, Broad Pipeline and Marketed Products**



	Pre-clinical	Phase I	Phase II	Phase III	Market/Registered	Also available as a Named Patient Product
Grass MATA		Short-course SCIT				
Tree MATA		Short-course SCIT				
Ragweed MATA	*	Short-course SCIT				
Bee Venom SCIT		Short-course SCIT				
Wasp Venom SCIT		Short-course SCIT				
Grass MATA MPL		Short-course Grass SC	IT with MPL			
Birch MATA MPL		Short-course Birch SC	IT with MPL			
Ragweed MATA MPL		Short-course Ragweed	I SCIT with MPL			
Trees MATA MPL		Short-course Tree SCI	T with MPL			
Oral Grass, Trees & House Dust Mite	Sublingual im	nmunotherapy with flexi	ble-dosing			
Modified Mite Platform	Short-course HDM SCIT +	modified Allergen MPL				
Peanut SCIT	Short-course Peanut SCIT					

VLP candidates under proof-of-concept evaluation for uses outside allergy including cancer, asthma, psoriasis and atopic dermatitis

**SCIT**: Subcutaneous Immunotherapy **MATA**: Modified Allergen Tyrosine Adsorbed

#### **Grass MATA MPL**

Trials to provide data for authorisation for Grass product in US and EU

Exploratory trial (G309) to be followed by efficacy field trial (G306) in US and Europe

Trial G309 started and will report in autumn 2021

Grass Phase III efficacy trial (G306) to start H2 2022 to allow learnings from G309.

Only one Phase III efficacy trial and completion of safety database away from filing in US

Both trials (G309 and G306) fully funded

Key product for US introduction – Ragweed and Birch would be products to follow with INDs already open and Phase II data available



#### **VLP Peanut product**

Single dose of virus like particle (VLP) with recombinant peanut allergen successfully protects against anaphylaxis when challenged with peanut in animal model

Data sharing contract signed with VLP partner which could significantly ease development of the peanut product through clinical trials

Safety profile of product evaluated and found **not** to induce anaphylaxis

Industrial scale-up progressing well with ex vivo trial with Imperial College in winter of 2020

Peanut represents a new opportunity into \$8bn\* worldwide food allergy market

First in vitro human trial planned to begin H1 2022. Initial trial fully funded

**Allergy** Therapeutics PLC First in human study planned to begin H1 2022

\*The Journal of Allergy and Clinical Immunology 2016. 1% of US population. EACCI Food Allergy and Anaphylaxis Guidelines Group 2016 0.2% of Western European Population. Management assumption of annual treatment of \$2k

#### Increased investment in VLP Technology

- Exclusive licence agreements signed to use patented VLP technology platform to develop vaccines targeting oncology and immune conditions –
  - Cancer
  - Asthma
  - Atopic Dermatitis
  - Psoriasis
- Leveraging known technologies VLP, vaccines, immunology and adjuvant systems
- Plan to evaluate via initial pre-clinical evaluation. If successful, will explore future clinical development and potential partnering opportunities



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# Expanding in Europe

#### Solid sales growth of 7% at constant rates in 2020

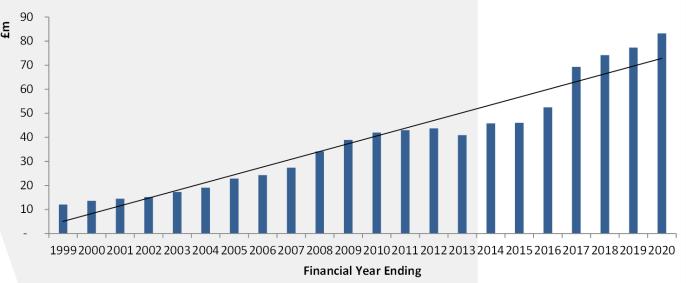
Good growth tempered by impact of COVID, especially in Southern Europe Rapid response to COVID with support for doctors and nurses

Focused cost efficiencies while investing in future

Continued strong performance of supply chain

Further strengthening of broad portfolio and capabilities with ImmunoBON and Immunolab in Alcala

9% CAGR growth over last 22 years since formation



Gross Revenue (excludes rebates)

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# Preparing for US entry

#### Allergy Therapeutics PLC

## The changing US regulatory landscape offers potential for significant commercial growth

#### Current US SCIT market



- Home made, unlicensed preparation
- Non GMP manufacturing
- Non registered
- No clinical evidence
- Long courses of treatment:50 to 100 injections
- Slow to act: 6 to 12 months
- Low compliance

New USP and FDA regulations drive towards pharmaceutical grade, centrally manufactured, single allergen treatments

#### Allergy Therapeutics' entry in the US



- Standardised dose vaccine
- GMP manufactured
- FDA submission
- Multiple clinical studies
- Ultra- short course treatment:
   6 injections for optimal product profile
- Efficacy in 3 weeks
- High compliance





16% Some adherence levels as low as 16%\* 2-3m
Americans receive allergy immunotherapy\*\*\*



Currently no registered injected products



\*Hankin CS, Cox L, Lang D et al 2007 JACI

\*\* Internal estimate

\*\*\* Professor Lawrence DuBuske MD

### Capturing the opportunity

New USP and FDA regulations drive towards pharmaceutical grade, centrally manufactured, single allergen treatments

#### **Building on progress to date**

- \$100m invested in clinical studies to date
- 15 clinical trials completed to date, including Phase I, II & III successful studies
- Investigated in over 3,000 patients worldwide, mainly in the US

# Allergy Therapeutics PLC Summary and outlook

#### 2020 financial and operational highlights



Expanding pipeline

VLP technology

Oncology and immune conditions

7% constant

increase in revenue to

£78.2m (2019 £73.7m)

**Grass MATA MPL** 

**Exploratory Field Trial** 

Starting in Germany and US in H2 2020

Operating profit pre R&D up 25%

Increase in net profit of 104% to £7.1m

One-off legal expenses claim of £3.2m settled

Cash balance of £37.0m

Strengthening portfolio

**ImmunoBON** 

Initial launch expected in Spring 2021

#### 2021 set to be an important year

**Delivering against our strategy**: three pillars to growth

Progression of clinical trial for Grass MATA MPL for European and US market

First in human cell VLP peanut study in 2021 and in-human trial H2 2021

Drive further growth in sales including launch of ImmunoBON

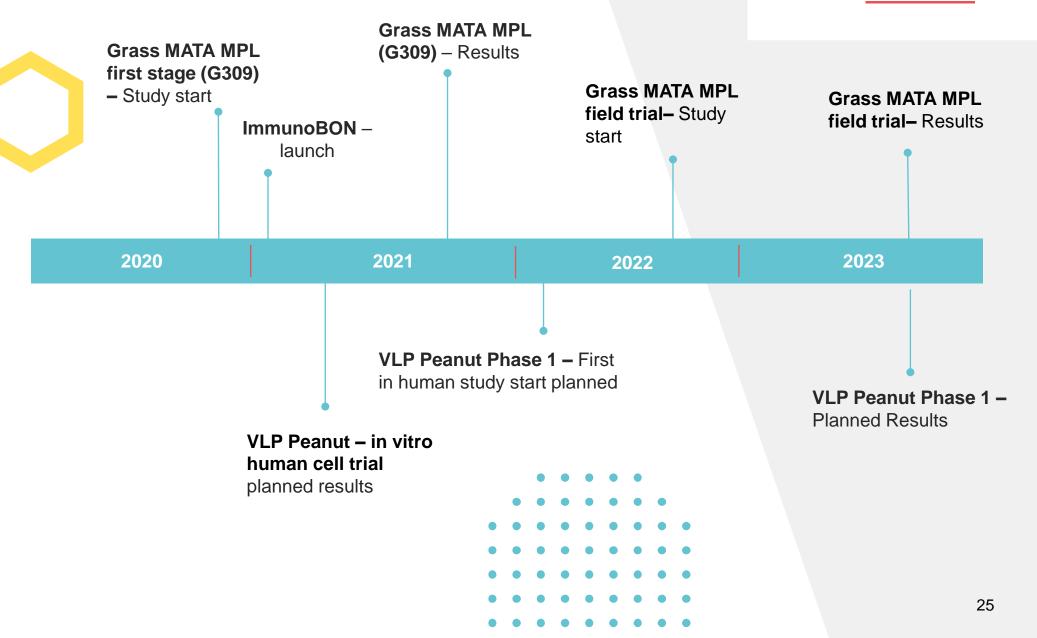
Focused strategy to be first to market in the US SCIT segment







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Q&A

